



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Precedent
7B
MW

In re the application of: Tony Baker

Application No.: 09/805,785

Filed: March 13, 2001

For: *Methods and Reagents for Preservation of
DNA in Bodily Fluids*


Attorney Docket No.: SDB-001CN

Group Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

Commissioner for Patents
Washington, D.C. 20231

Attn: Initial Patent Examination Division
Customer Service Center

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| Date of Deposit: <u>July 24, 2001</u> | CERTIFICATION UNDER 37 CFR 1.10 | Mailing Label Number: <u>EL 683 637 995 US</u> |
| I hereby certify that paper or fee as enclosed are being deposited with the United States Postal Service on the date indicated above in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 and addressed to: Commissioner for Patents, Washington, D.C. 2023, Initial Patent Examination Division, Customer Service Center: | | |
| <u>Larry Taylor</u> |  | |
| Name of Person Mailing Paper | Signature of Person Mailing Paper | |

**PRELIMINARY AMENDMENT AND
RESPONSE TO NOTICE TO FILE CORRECTED APPLICATION PAPERS**

Dear Sir:

This document is submitted in response to the Notice To File Corrected Application Papers mailed from the United States Patent and Trademark Office on May 24, 2001. Please amend this application as follows:

In the specification:

✓ Please delete the paragraph on page 8, lines 5-7:

B -- Figure 19 illustrates the synergistic effect obtained by the combination of the components of the inventive reagents in protecting gonococcal DNA in urine stored at room temperature and subsequently subjected to PCR detection.--

Please replace the paragraph on page 12, lines 7-17 with:

B Figure 18 illustrates the relatively weak preservative effect on gonococcal DNA in urine stored at room temperature and subsequently subjected to PCR detection offered by the individual addition of components of the reagents of the present invention, i.e., divalent metal chelators 0.01M BAPTA (18A), 0.01M EDTA (18B), 0.01M EGTA (18C); and chelator enhancing components 1M sodium perchlorate (18D), 1M salicylic acid (18E), 1M guanidine HCl (18F), 1M sodium thiocyanate (18G), and lithium chloride (18H). The number of transformants in ten types of urine specimens were tested using a GTT, counted hourly, and then summarized. The standard Gonostat protocol (*see* Example 2, *infra*) was employed and illustrated the synergistic effect obtained by the combination of divalent metal chelators and chelator enhancing components in protecting gonococcal DNA in urine stored at room temperature and subsequently subjected to PCR detection.

Please replace Table 3 at the top of page 18 with:

Table 3

| <u>Function</u> | <u>Name</u> | <u>Nucleotide sequence 5' to 3'</u> | |
|-----------------|-------------|-------------------------------------|---------------|
| Primer | PPNG-L | AGT TAT CTA CAC GAC GG | (SEQ ID NO:1) |
| Primer | PPNG-R | GGC GTA CTA TTC ACT CT | (SEQ ID NO:2) |
| Probe | PPNG-C | GCG TCA GAC CCC TAT CTA TAA ACT C | (SEQ ID NO:3) |

Pursuant to 37 CFR 1.121(b)(1)(iii) and 37 CFR 1.121(c)(1)(ii), a marked up version of the amended text showing the changes made appears herein as Appendix A.

REMARKS

The Notice to File Corrected Application Papers (Filing Date Granted), mailed May 24, 2001, indicates that *substitute* drawings in compliance with 37 C.F.R. § 1.84 are required. The Notice further indicates that a computer readable form of the Sequence Listing is required in compliance with 37 C.F.R. § 1.821(e).

The specification has been amended to remove reference to "Figure 19". Claims 1-21 will remain pending in the application upon entry of the amendments presented herein. Applicants also submit herewith in response to the Notice to File Corrected Application Papers substitute drawings in compliance with 37 C.F.R. 1.84.

Accordingly, Applicant submits herewith fourteen (14) sheets (Figures 1-18G) of substitute drawings. Applicant submits that the formal drawings are in compliance with 37 C.F.R. § 1.84.

Also, in accordance with 37 C.F.R. § 1.825, Applicant submits herewith one (1) page which contains a Sequence Listing for the above-referenced application, and submits (concurrently herewith to BOX SEQUENCE a computer-readable form (diskette) of the Sequence Listing which

is identical in substance to the paper copy of the Sequence Listing submitted herewith. No new matter has been added. Accordingly, as the above submission does not affect the issue of patentability, it is respectfully requested that the paper and computer-readable versions of the Sequence Listing be entered.

In view of the amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicant's Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

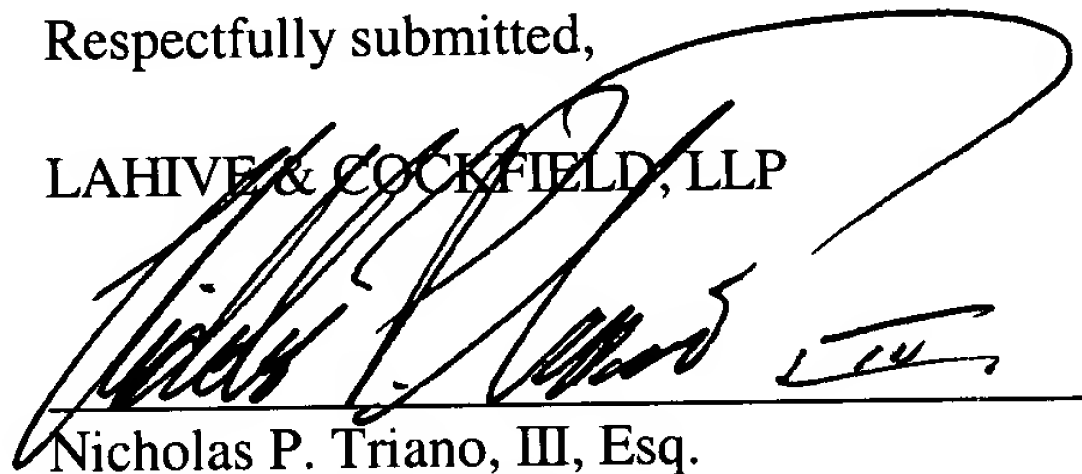
SUMMARY

In view of the amendments and remarks presented herein, Applicant believes that this application is in condition for allowance. If a telephone conversation with Applicant's attorney would expedite the prosecution of this application, the Examiner is urged to call Applicant's attorney at (617) 994-0773.

Attached hereto as Appendix A is a marked-up version of the changes made to the claims by the current amendments. Appendix A is captioned "**Version with markings to show changes made.**"

Respectfully submitted,

LAHIVE & COCKFIELD, LLP

A large, stylized handwritten signature in black ink, likely belonging to Nicholas P. Triano, III, Esq., is written over the firm name and extends across the signature line.

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Dated: **July 24, 2001**